DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2014

SIGNUS Medizintechnik GmbH
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K141405
Trade/Device Name: MOBIS®II ST Spinal Implant
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 12, 2014
Received: June 18, 2014

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141405

Device Name

MOBIS®II ST Spinal Implant

Indications for Use *(Describe)*

The MOBIS®II ST Spinal Implant is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). MOBIS®II ST Spinal Implants are to be used with autogenous bone graft and implanted via an open posterior or transforaminal approach. The MOBIS®II ST Spinal Implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*5*10(k) Summary
for the MOBIS®II ST Spinal Implant

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the MOBIS®II ST Spinal Implant

1. GENERAL INFORMATION

Date Prepared: June 12, 2014

Trade Name: MOBIS®II ST Spinal Implant

Common Name: Interbody spacer

Classification Name: Intervertebral body fusion device – lumbar

Class: II

Product Code: MAX

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed Predicate Device:
MOBIS® Spinal Implant (K131372)
T-PAL Spacer (K100089)
Lucent Straight Cage (K071724/K081968)

Submitter:
SIGNUS Medizintechnik GmbH
Industriestrasse 2
D - 63755 Alzenau
GERMANY
Joachim Schneider
+49(0)6023 - 9166 - 213

Contact:
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

The MOBIS®II ST Spinal implants have a hollow, slightly curved frame with areas of an open-pore titanium grid structure. Restoration of the intervertebral space can be achieved by the large selection of implants that, at the same time, offers a high degree of intraoperative flexibility. In addition to straight implants, the MOBIS®II ST cage is also available with a 5° lordotic angle. Due to its design, the implant can be aligned with the anterior curvature of the intervertebral body and so is suited for unilateral, dorsal access (TLIF) in the L2 to S1 region of the spine.

Materials:

Titanium alloy (Ti6Al4V) (ASTM F136)

Function:

Maintain adequate disc space until fusion occurs.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The MOBIS®II ST Spinal Implant is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The MOBIS®II ST Spinal Implant is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). MOBIS®II ST Spinal Implants are to be used with autogenous bone graft and implanted via an open posterior or transforaminal approach. The MOBIS®II ST Spinal Implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM F2077
- Static and dynamic compression-shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of this testing indicate that the MOBIS®II ST Spinal Implant is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

SIGNUS Medizintechnik considers MOBIS®II ST Spinal Implant to be equivalent to the predicate devices listed in section 1. ‘General Information’. This conclusion is based upon the device's similarities in principles of operation, technology, materials and indications for use.